

REMARKS

In view of the amendments to the claims and the remarks set forth below, reconsideration and allowance are respectfully requested.

FORMAL MATTERS

Claims 5-20 are pending. Claims 5-12 are withdrawn from consideration. Claims 1-4 stand previously canceled without prejudice. Claims 5, 8, 10 and 11, although withdrawn, are amended to correct minor and obvious typographical errors.

In the previous response, claim 13 was amended to recite "A gene mapping method, comprising: selecting a combination of DNA sequences comprising SEQ ID Nos. 1-27088 ...". Claims 13, 14, 16, 17, 18 and 19 are currently amended for clarity as set forth below.

Claim 13 is amended to provide antecedent basis for the phrase "microsatellite markers found positive" recited in dependent claims 18 and 19. Support for this amendment may be found in the published PCT specification, at least, for example, at paragraphs [0298], [0135], [0255], and [0256]. In one embodiment, the gene mapping method of the present invention is conducted by comparing the frequency of microsatellite genetic polymorphic markers in healthy control subjects with the frequency observed in randomly selected affected patients (paragraph [0100]). The microsatellite markers that indicate statistically significant differences in frequency during a correlation analysis are referred to as "positive" (*see, for example*, paragraph [0134]).

Claims 17 and 18 are amended for clarity to recite a method comprising second screening in order to reduce the number of false positives, and to identify microsatellite markers of true-positives (*see, for example*, paragraph [0134]).

Claim 19 has been divided into two multiply dependent claims, the first reciting a method in which the DNA segments comprising a microsatellite marker found positive in the first screening (claim 13) are analyzed using known single nucleotide polymorphisms. Basis for this amendment may be found in the published PCT specification, at least, for example, at paragraph [0135], and Examples 1-5. New claim 20 finds basis in original claim 19 and in paragraph [0135] of the published PCT specification. The new claim recites that the microsatellite markers found true positive in the second screening (claims 17 or 18) are analyzed using known single nucleotide polymorphisms.

No new matter is added by way of these amendments.

RESTRICTION REQUIREMENT

In the Office Action dated February 27, 2007, the Examiner stated that claims 13-19, which were recently amended in the filing of January 25, 2007, do not correspond to the invention elected in response to the restriction requirement submitted November 16, 2005. Applicant would like to draw the Examiner's attention to the summary of telephonic interviews conducted January 8, 2007 and January 24, 2007 between Applicant's representative, Geri Rochino, and Examiner Kapushoc. There, the Examiner noted that although claims directed to a combination of DNA sequences comprising SEQ ID Nos. 1-27088 could not be rejoined with the claims pending at the January 25, 2007 stage of prosecution, such claims would be entered upon the filing of a subsequent Request for Continued Examination ("RCE"). *Attached herewith is Applicant's RCE and associated fees.* Thus, Applicant respectfully asks the Examiner to enter the amendments presented in the filing of January 25, 2007, and to examine said amended claims on the merits.

Moreover, Applicant emphasizes that M.P.E.P. § 803.04 instructs the Examiner to waive the requirements 37 C.F.R. § 1.141 ("Distinct inventions may not be claimed in one national application") with respect to the subject matter recited in claim 13. Specifically, in 1996 the Office Director *sua sponte* waived the presumption in certain cases that each nucleotide sequence is presumed to represent an independent and distinct invention, subject to restriction. One of these cases is where a claim is presented in the format: "a combination of DNA fragments comprising SEQ ID Nos. 1-1,000," *see* M.P.E.P. § 803.04. In this example, the Office requires that the entire combination be searched until one nucleotide sequence is found to be allowable. Further, "[t]he identification of any allowable sequence(s) will cause all combinations containing the allowed sequence(s) to be allowed," *Id.*

In the previous response, claim 13 was amended for clarity to indicate that they include a combination of nucleotide sequences (SEQ ID Nos. 1-27088), in accordance with the example set forth above ("A gene mapping method, comprising: selecting a combination of DNA sequences comprising SEQ ID Nos. 1-27088...". As described in Example 1, paragraph [0251] of the instant specification, each of the sequences in the combination were used to prepare a forward and reverse primer and PCR was performed using forward (5'→3') and reverse (3'←5') primers having nucleotide sequences based on each of the sequences in the combination. Accordingly, per M.P.E.P. § 803.04, no Restriction Requirement should be applied to the present claims.

PRIORITY

The Examiner states that claims 13-19 have been awarded the effective filing date of September 26, 2003, which corresponds to the filing date of this CIP application, as the parent application (U.S. Serial No. 10/257,511) and the English translation of the priority documents do not disclose the sequences represented by SEQ ID Nos. 1-27,088. We note, however, that the certified copy of the priority document (JP 2002-383869, filed on December 9, 2002) included a CD-ROM containing the sequence listing for SEQ ID Nos. 1-27,088. Therefore, the effective filing date of the present application is December 9, 2002.

CLAIM OBJECTIONS

Claim 13 has been objected to for lacking the connector "and". Appropriate correction has been made. Therefore, withdrawal is respectfully requested.

REJECTIONS UNDER § 112, ¶2

Claims 17-18 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite in the recitation of "markers found positive" for lack of a clear antecedent basis. This rejection is addressed by amendment and may be withdrawn.

Claim 19 was also rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of "based on single nucleotide polymorphisms". This rejection is addressed by amendment and may be withdrawn.

REJECTIONS UNDER §§ 101 AND 112, ¶1

Claims 13-19 have been rejected under 35 U.S.C. § 101, and under § 112, first paragraph, for allegedly lacking a specific utility and enablement, respectively. In particular, the Office Action states that the specification does not teach an association between the microsatellite markers of SEQ ID Nos. 1 and 2 and any specific phenotype or specific gene associated with a particular phenotype. This rejection is traversed as applied and as it may be applied to the presently pending claims.

As to the pending claims, the recited subject matter is directed to new methods of association analysis in which susceptible genes for multifactorial or complex diseases are identified by genome-wide screening. The methods encompass identifying new pathogenic genes and regions of such genes associated with a disease (a human phenotype associated with a genetic factor). Similar to methods of screening agents against a target to identify their activity as a drug, the present methods provide methods for screening to identify genes and gene fragments associated with a disease.

In order to identify the susceptible genes for complex diseases, the sequences represented by SEQ ID Nos. 1-27088 are not used separately but as a single set of 27,088 sequences, with each containing at least one microsatellite marker. Thus, each of the sequences represented in claim 13 should not be viewed as a distinct invention, but rather as part of a gene mapping method using a set of sequences of SEQ ID Nos. 1-27088.

With the filing of the Request for Continued Examination that accompanies this response, it is requested that the Examiner incorporate Applicant's previous amendments into claim 13, and thereby examine it and its dependencies on the merits. Accordingly, as stated in the interviews of record, with the filing of this RCE, and the entry of the amendments set forth herein, the rejections under 35 U.S.C. §§ 101 and 112, first paragraph should be withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number WING-003CIP.

Respectfully submitted,
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